REMARKS/ARGUMENTS

In the Final Office Action, the Examiner noted that: Claims 1-7 are pending the application, of which Claims 1-7 are rejected. The claims have been amended as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Response to Office Action Paragraphs 1-4
Claim Rejection Under 35 U.S.C. §112

In the Office Action the Examiner rejected Claims 1-4 under 35 U.S.C. §112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner stated that "Regarding claim 1, nowhere in the specification discloses a frame having a radiopaque material that varies in thickness over an axial length of the midsection of the cylindrical frame."

By the present amendment, Applicants have amended Claim 1 to recite in part: "wherein said frame is formed from material comprising radiolucent material, wherein the forming material varies in thickness over an axial length of the cylindrical frame, so that the radiopacity of the frame varies correspondingly."

Support for this amendment can be found in the application as originally filed, including page 21 lines8-32 (e.g., "prosthesis made from stainless steel").

Applicants believe that this amendment obviates the rejection and respectfully request withdrawal of this rejection and the allowance of Claim 1 and all those depending directly or indirectly therefrom.

Response to Office Action
Claim Rejection Under 35 U.S.C. §102(e)

In the Office Action the Examiner rejected Claims 1 and 4-7 under 35 U.S.C. §102(e) as being anticipated by Lashinski et al (USPN 6,071,296).

More particularly, the Examiner referencing Column 5, lines 63-66 and Column 6, lines 1-5, noted that "Lashinski et al discloses a stent made of radiopaque material wherein the radiopaque material is thicker near the ends of the cylindrical frame than over the midsection."

Lashinski et al is directed to a stent comprising an expandable, generally tubular body portion in which one or both ends of the stent are provided with a generally rounded, smooth radiused portion that forms a bulbous protrusion out of the plane of the circumference of the stent (Abstract). In describing the material for forming the stent, the specification describes that "[t]he stent and radii are preferably formed from radiopaque materials. Since there typically is more material in the end regions of the stents of the present invention compared to the stents of the prior art, the increased amount of radiopaque material at the ends of the stent are more clearly outlined during deployment, thereby assisting accurate placement of the stent." This description is more particularly directed to those embodiments (such as FIG. 5) wherein more material 54 is added in the regions of apex 52 of the stent (Column 4, lines 60-63) or by thickening the stent (Column 5, lines 15-17), increasing the profile of the apex 52.

Lashinski et al further states on Column 5, lines 63-66 and Column 6, lines 1-5, as noted by the Examiner, that "[t]he stent and the radii are preferably formed from radiopaque materials," and "[s]ince there typically are more material in the end regions of the stents ..., the increased amount of radiopaque material at the ends of the stent are more clearly outlined during deployment".

By the present amendment Claims 1 has been amended to recite, in part: "... frame is formed from material comprising radiolucent material, wherein the forming material varies in thickness over an axial length of the cylindrical frame, so that the radiopacity of the frame varies correspondingly"; and Claims 5-7 have been amended to recite, in part: "... frame formed from a material comprising a radiolucent material ... ."

In contrast to Lashinski et al., Claim 1 and Claim 5-7 as presently amended, are directed to a prosthesis formed from a material comprising a radiolucent material." Stainless steel, as disclosed in the specification of the present application, is a radiolucent material, as also referred to in the cited reference Callo column 1 lines 26-29.

Lashinski et al. does not disclose a prosthesis formed from a material comprising a radiolucent material. The stent of Lashinski et al is made of a radiopaque material which by virtue of a greater thickness at the distal ends has a greater radiopacity at the ends.

Applicants submit that Claims 1 and 5-7 are not anticipated by or obvious in view of Lashinski et al., and that they are patently distinguishable over the same. Applicants respectfully request the withdrawal of the rejection and request allowance of Claims 1 and 5-7 and all those Claims depending directly or indirectly therefrom.

Response to Office Action
Claim Rejection under 35 U.S.C §103

The Examiner rejected Claims 2 and 3 under 35 U.S.C §103 as being unpatentable over Lashinski et al (USPN 6,071,296), in view of Callol et al (USPN 6,174,329).

In rejecting the claims, Examiner stated that "Lashinski et al discloses the invention substantially as claimed. Additionally, Lashinski et al. discloses a stent that can be altered and be changed with different material composition (e.g., metal or non-metal) (see column 4 lines 64-67). However, Lashinski et al. does not disclose a frame made of stainless steel and a coating made of gold, platinum, etc."

The Examiner further stated that "Callol et al. teaches a stent having a frame made of stainless steel and a coating made of gold, tantalum, etc., so it can twist and deform easility and it can be seen from a fluoroscope." The Examiner then concluded that "It would have been obvious to one having ordinary skills in the art at the time the invention was made to alter and changes the material composition of the frame with the stainless steel core and gold coat of Callol et al. reference in order to change the material property of the stent so it can deform more easily and it can be seen from a fluoroscope."

Applicant submits that Claims 2 and 3 as Claims depending directly or indirectly from Claim 1 are patentable.

Assuming arguendo that Claim 1 were not patentably distinguishable over Lashinski et al Applicant submits that Claims 2 and 3 are nevertheless patenable over Lashinski et al alone or in combination with Callol et al.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" *In re Fritch, 23 USPQ 2d 1780, 1783 (Fed. Cir. 1992) quoting In re Fine, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988).*

Applicant respectfully submits that a prima facie case of obviousness has not been established. There is no objective teaching for changing the material of Lashinski et al to that of the Callol et al. The stent of Lashinski et al is entirely made of radiopaque material with the objective only being to provide a less traumatic device. The stent of Callol et al is made of two different material, a sufficiently radiolucent material and a thin layer of a radiopque material.

Assuming arguendo that a prima facie case of obviousness has been made, Applicant respectfully submits that the combination of the two reference is improper.

'A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See United States v. Adams, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966) ("known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness").' *In re Gurley, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994).*

Callol et al teaches away from using a variable thickness radiopaque material as for example noted on Column 5, lines 1-3, stating that "[t]hus, the thickness of the radiopaque

layer should be uniform and in the preferred thickness ranges ..., where it will be implanted, the diameter of struts 15, and the like."

Additionally, Callol et al teaches away from using the radiopaque material on those portions of the stent that are curved, as for example noted on Column 5, lines 21-24, stating that "... while stent portion 31, which is curved, is not covered by a radiopaque layer." The stent of Lashinski et al has the higher radiopacity at the radii having a generally rounded (i.e., curved) radius (Column 3, lines 18-19).

For all of the reasons stated above, Applicant submits that Claims 2 and 3 are patentably distinguishable over Lashinski et al alone or in combination with Callol et al, and requests the withdrawal of the rejection and allowance of the Claims 2 and 3.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is urged.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

Soodabeh Tronson
Reg. No. 41,354

by: James M. Heslin
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
JMH:jke
PA 3314944 v1